



From: Leslie A. Beben
5805 Brookland Drive
Sumter, SC, 29154

11/3/05

To: United States Patent and Trademark Office
Commissioner For Patents
P.O. Box 1450
Alexandria, Virginia, 22313-1450

101765639

Attention: Examiner Dana D. Greene

Subject: Response to Rejection of Claims
Patent Application # 20040186522
Attorney Docket #COM002USPTO1
Confirmation #1213

Preface: I appreciate your prior review of my work. I am an independent inventor and lifelong student of heart disease. It is my understanding that your Art Unit, #3762, holds primary responsibility for protection of intellectual property relevant to inventions seeking mechanistic control of systole and diastole in heart disease in this country. Following extensive review and barring reading of unpublished applications, I remain unaware of an invention that would attempt to seize control of electrical myocardial systole in a retrograde manner from the pericardial space. In my opinion, transmyocardial (transmural) mechanistic electrical control of myocardial mass is technically imminent.

Theory:

1. This device is based upon theory and is of little value unless proven to make a sizable and inexpensively measured contribution to myocardial performance.
2. Prior language in claims quoted as "normal contraction of the heart" is understood to mean systole.
3. Definition of systole is further understood to include performance elements driven by electricity and blood weighted to specified physiology in health as well as pathology.
4. Abrupt loss of secondary, autonomic control of the myocardium is traditionally and surgically apparent in heart transplantation.
5. Gradual, insidious loss of autonomic control of the myocardium to a host of pathological processes is less well understood.
6. Areas of identified electrical insufficiency within the myocardium may be theoretically "bypassed" if a means to achieve this intervention in such a presumed entity were mechanistically possible.
7. Proposed theory posits that myocardial mass is dependent upon optimal electrical propagation timed and tied to blood perfusion in almost equal ratios applied to myocardial performance.

8. Extravascular application of a circumferential artificial electrical field surrounding the myocardium from an externally applied grid at the epicardial interface represents a novel means of electrical control of the myocardium.

9. Implied myocardial control from an "outside in" perspective compared to traditionally studied "inside out" electrical control of the myocardium is believed to represent a restorative step in replacing lost contribution of undead cardiomyocytes marginally committed to performance.

10. The submitted invention seeks to restore a retrograde and concurrent means of selective global depolarization of the myocardium when and where sinoatrial induction of electrical systole is found to be clinically and computationally insufficient in individualized failure states.

11. An expedient model in understanding the utility in such a device is represented in medical terms as "nonischemic cardiomyopathy". This is a widespread clinical conundrum of many entities unapproachable by vessel bypass, stents and applied neovascular growth factors.

12. I posit that a substantial subset of these patients suffer from myocardial autonomic insufficiency amenable to retrograde recovery of myocardial performance lost to adequate blood perfusion.

13. The device will allow meaningful physiologic study and computational analysis and intervention in many disease states allowing many other inventions applied to data sent.

14. Suturing of the device to the pericardium is *abandoned* in favor of the approach originally filed 1/27/03. The original intention was that the device be "attached and secured to itself only and shall not allow suturing of the myocardium."

Intellectual Property:

Novel intellectual property in these claims is represented by a device that will introduce retrograde, concurrent propagation of electrical energy to areas of pathological failure of the myocardium unaddressed by known pacing technology.

Background and Law:

1. I am a small fish in a very large pond and cannot hope to match the legal resources of the entities I have discussed this application with in the preceding years.

2. All current pacemakers, ICDs, LVADs, etc. known to me within the art arrive at their destination from an intravascular, blood-exposed environment.

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9. Work known to Shapland in my Provisional Application # 60/442/480 filed 1/27/03 was not addressed in this ruling.

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14. Dr. Shapland and I subsequently held several telephone and e-mail discussions regarding this application.

15. My request for collaboration with Acorn regarding this Application was ultimately rejected. (Attachments #2 and #3)

#15 16. In the midst of these exchanges, Shapland, et. al. filed Utility Application US2003/0199733 on 6/2/03.

Review of Provisional Application #60/442/480

Given consideration of the above information, I respectfully request further explanation of the submitted provisional patent as follows.

1. **“Description of the device: a. The device shall fit like a fishnet over the epicardial surface and roots of the great cardiac vessels. It shall be applied to a heart of any dimension.”**

Crossing strands of filaments large and small abound in description at the USPTO and include textiles, fishnets and fences. Electrical fences are a step ahead in an older technology realizing newer potential. Art relevant to containing uncooperative livestock with electric filaments is apparently very different from prior art espousing passive restraint of same. A review of the USPTO database from 1790 to present db for “TTL/fence AND electric” reveals 96 awarded patents in this pursuit.

2. **“Description of the device: c. The device shall allow placement of a conformable mesh which is capable of propagation of electrical current throughout it's embodiment.”**

Given provisional dating and prior art reviewed, I firmly believe I was the first to state this.

3. "Claims: c. Attempt coordinated, sequential propagation of current through the grid to amplify desirable autonomic propagation and maximize ejection fraction. The device shall similarly endeavor to reject all reentry phenomena within it's reach."

To my knowledge, ~~this~~ this is the first public mention of myocardial autonomic insufficiency and first to announce capability of mechanistic intervention of same.

4. "Claims: d. Allow independent right and left sided electrical manipulation of said grid to allow regulatory mechanisms for forward and backward failure."

This concept implies considerable computational application in beat to beat application but would be very straightforward in a device linked to a suitable driver. I believe this conceptual model of optimal left/right control will surpass current internally pursued methods known in the art to attempt restoration of ventricular dyssynchrony.

5. "Claims 2. For the indication of cardiac conduction disease, the device shall:

a. Allow placement of an electrical grid which engrafts to the entire epicardial and /or parietal animal pericardial surface. This embodiment shall be modifiable to include at least partial to almost total external coverage by the fibrous pericardium."

I reject the word "engrafts" in this claim as I now believe this property is akin to an incision in healthy tissue.

6. "Claims 2b. Allow targeted propagation of electrical energy throughout it's mesh."

This is what active restraint (an electric fence) does that passive restraint (a fence) does not.

7. "Claims 2d. Attempt external amplification of existing autonomic circuits." Announces retrograde amplification of electrical systole as an achievable goal.

Reflections:

1. Iatrogenic is a difficult word and means many things. I believe it means what happens as we do our technical best in trying to achieve a desired physiologic effect. It isn't good or bad, just an overall descriptive term relevant to law in device therapy.

2. Approaches in device therapy representing punctures, incisions and engraftment of the pericardium, epicardium, myocardium and endocardium by any device for any purpose to any depth are clear examples of iatrogenically feasible fields of study.

3. Myocardial device therapy immediately implies the ability and skills of a cardiac surgeon, interventional radiologist or interventional cardiologist.

4. Claims that violate healthy tissue by iatrogenic means (incisions, ablation, engraftment) block forthcoming progress in medicine and surgery.

5. Fibrosis, restrictive pericarditis, and similar negative rendering of degradation of diastole from an iatrogenic device should be considered unacceptable.

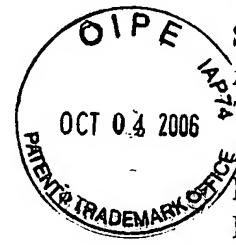
6. Recent regulatory proceedings dictate that redundancy in achieving and maintaining control of a device-driven iatrogenic effect must be paramount in engineering same.

Close: I thank the USPTO for this review. It is my hope that I have provided a clearer explanation of the proposed capabilities and novel potential of the submitted intellectual property. Given the perspective of systole as an entity amenable to device driven amplification of desired autonomic propagation, I humbly request that the examiner recognize my ownership of the contested intellectual property in my provisional filing dated 1/27/03.

Sincerely,

Attachments:

1. E-Mail from Clif Alferness dated 4/16/03
2. Letter from Dr. J. Edward Shapland dated 5/2/03
3. Letter from Dr. J. Edward Shapland dated 6/16/03



Subject: Response of Applicant to Notice of Abandonment

9/26/06

Applicant: Leslie A. Beben

To: United States Patent and Trademark Office

Application Number: 10/765639

Examiner: Angela D. Sykes

Initial Examiner: Dana D. Greene

Fax #: 703-872-9306

Ms. Sykes, I greatly appreciate you taking the time to speak with me by telephone last week about this application. I regret that examiner Greene no longer works at the USPTO. Attached is a copy of the response I sent personally addressed to Ms. Greene on 11/3/05. I affirm that this copy is a duplicate of the prior letter sent.

My best copy (attachment #1) that matches your copy has added handwritten references in the margins to correct typographical errors. Attachment #2 comprises three letters I received from Acorn in 2003 as noted below. I modified the letter the same day I sent it to remove the typographical errors. The corrected version (attachment #3) is essentially the same document without clutter.

I personally spoke with Ms. Greene by telephone about this application and promise you that you already have this communication. I am quite concerned that it cannot be immediately verified and am frankly a little worried about the confidentiality of the disclosed information.

I would like to speak with Ms. Greene again if this is possible. I am still checking through my postal records but I send most everything by Certified US Mail. I have had lengthy waits in the past for an answer to some of my stuff from the USPTO but must admit I was still getting concerned that something about this one had gone awry. Please feel free to contact me for any questions.

Leslie A. Beben
5805 Brookland Drive
Sumter, SC, 29154

Home: (803) 494-9596

Work: (803) 452-5151

Attachments:

#1 Copy of letter sent to Dana D. Greene 11/3/05

#2 Copies of letters from Alfernness 4/16/03, Shapland 5/2/03, 6/16/03

#3 Copy of corrected letter to Dana D. Greene 11/3/05 with typos removed

**Main Identity**

From: "Clif Alferness" <calferness@scoutmedical.com>
To: <lbeben@sc.rr.com>
Sent: Wednesday, April 16, 2003 1:29 PM
Subject: your email

Hi Les,

Tracy Kaestner has told me about your earlier email regarding your ideas on a pericardial augmentation device. I did receive your letter and only briefly glanced through the material to see what it was about. My impression is that it is in an area already covered by numerous patents owned by Acorn. You may, however, want to contact them to see if there are any aspects covered by your application that they have an interest in. The person that you should contact there is Dr Ed Shapland. Although we, at Scout, have no relationship with Acorn Cardiovascular, I am personally still associated with them, but only as a board member. As such, I would encourage you to contact Dr Shapland (eshapland@acorncv.com) to satisfy your query.

Clif Alferness
Partner, Scout Medical Technologies
4030 Lake Washington BLVD, #305
Kirkland, WA, 98033
425 827 4300 ext 224
calferness@scoutmedical.com



acorn
cardiovascular, inc.

2 May 2003

Leslie A. Beben
5805 Brookland Drive
Sumter, SC 29154

Dear Mr. Beben:

Thank you for your fax of 17 April 2003.

Acorn Cardiovascular has developed procedures to review concepts submitted by non-employees. These procedures are developed to protect Acorn in the event someone submits an idea already known to us. Namely, we are frequently aware of ideas or have such ideas in development at the time someone suggests a concept to us. Therefore, we cannot review an idea submitted to us without the submitter acknowledging that our review is not an agreement to accept an idea and we do not have any obligations with respect to ideas already known to us or others or any obligations of confidentiality with respect to submitted information.

Before reviewing your idea, we wanted to make you aware of our practices. If you would still like us to review the idea, please indicate your approval on a copy of this letter and fax it back to me.

Also, we encourage people such as you to seek independent opinion of patent counsel for protection of ideas.

Best regards,

J. Edward Shapland, PhD
Sr. Vice President
Chief Technical Officer

Agreed to by:

Leslie A. Beben



acorn
cardiovascular, inc.

16 June 2003

Les Beben
5805 Brookland Drive
Sumter, SC 29154

Dear Les:

Thank you for the opportunity to review your provisional patent application entitled Pericardial Augmentation. As we discussed by phone, we have evaluated your concept based on its technical feasibility, prior art and fit with Acorn's primary focus.

At this time, we elect not to pursue license of this application. If you expand specific areas related to our core business, we would be happy to renew our discussions.

It was a pleasure to speak with you. Thank you again for forwarding this information.

Best regards,

J. Edward Shapland, PhD
Sr. Vice President
Chief Technical Officer

bjj



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